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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/007,385	01/15/98	CHU	H 0632/0D916

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DARBY & DARBY  
805 THIRD AVENUE  
NEW YORK NY 10022

EXAMINER

TURNER, S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/03/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/007,385**

Applicant(s)  
**Hsien-Jue**

Examiner  
**Sharon L. Turner, Ph.D.**

Group Art Unit  
**1647**



☒ Responsive to communication(s) filed on 10-10-00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 2-21 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 2-21 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### **Response to Amendment**

1. The Examiner and Art Unit of U.S. Patent application SN 09/007,385 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1647.
2. The amendment filed 10-10-00 has been entered into the record and has been fully considered.
3. Claims 2-21 are pending.
4. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

### **New Rejections Necessitated by Amendment**

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 2-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 introduces the new language "and the composition having the property of inducing protective immunity against *Streptococcus equi* infection following *Streptococcus equi* challenge as compared to non-vaccinated horses." This language is confusing to the skilled

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artisan because the language fails to further limit or define the composition recited. Instead the language appears to imply a method step of administration and challenge. The skilled artisan recognizes that the property of protective immunity as it pertains to a host but does not recognize such property of a composition. Thus, it is unclear to the skilled artisan what the claim intends to recite with respect to the composition. The language has thus been interpreted by the examiner as non-limiting with respect to the composition claimed. If applicants intend to introduce method steps to the claims the claims should be rewritten to indicate the desired method steps.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2-21 stand rejected under 35 U.S.C. 103(a) as set forth in Paper No. 15 mailed 5-4-00, as being unpatentable over US Patent No. 5,183,659, Timoney et al, 2 February, 1993, in view of EP0786518 A1, Hartford et al, 24 January 1997, and US Patent No. 5,597,807, Estrada et al., 28 January 1997.

Applicants argue that the criterion of both the suggestion of making the present invention and the expectation of success in the prior art have not been met. Applicants suggest that the examiner confirms that Hartford does not teach the stimulation of mucosal immunity. In

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particular applicants suggest that Hartford lacks a teaching of the stimulation of mucosal immunity and that Hartford does not teach or suggest a composition comprising the *Streptococcus equi* strain in combination with an immunostimulant that has the property of inducing protective immunity in horses. Applicants argue that Hartford does not teach the challenge and testing of an efficacious vaccine in horses. Applicants argue that a person of ordinary skill in the art would not expect to enhance the protective immunity of a live vaccine in an animal if that vaccine had not been demonstrated to be protective for that animal. Applicants argue that Estrada does not explicitly state that Q. Saponin promotes mucosal immunity per se. Applicants argue that Estrada with Timoney and Hartford in no way render the claims obvious, that the examiner uses hindsight reconstruction and that Estrada and Hartford in no way make up for the deficiencies of Timoney. Applicants further argue that Estrada does not provide a teaching or suggestion to overcome the deficiencies of Timoney and Hartford and that Estrada neither suggests nor provides a reasonable expectation of success in obtaining the efficacious vaccine composition which induces protective immunity in horses.

Applicant's arguments filed 10-10-00 have been fully considered but they are not persuasive. Contrary to applicants suggestion, the examiner does not confirm that Hartford fails to teach the stimulation of mucosal immunity. Hartford EP0786518 teaches protection via a live attenuated nasal mucosa *S. equi* vaccine in combination with an immunostimulant which comprises Quil A (saponin) adjuvant to enhance the immune response of the host, see in particular p. 3, lines 39-46. Hartford does not expressly teach that Quil A saponin adjuvant has

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the property of stimulating mucosal immunity. However, we know it does based on Estrada for example. In addition, the skilled artisan recognizes as set forth in Timoney et al., Recent advances in streptococci and streptococcal diseases (1985) pp. 294-5, Proceed. Of the IXth Lancefield Int'l Symp. on Strep. and Strep. Diseases, Japan, September 1984, Reedbooks Ltd., Chertsey., that cumulative findings suggest that successful vaccination requires stimulation of the nasopharyngeal immune response and that vaccination with 709-27 stimulates IgA and IgG antibodies even in the absence of Q. Saponin adjuvant, see in particular Figure 1. The stimulation of IgA and IgG by Q. Saponin is known as evidenced by Estrada which teaches enhanced IgA and IgG production, an effect which equates to the stimulation of mucosal immunity. Therefore, there is a strong suggestion that since Hartford is protective that the nasal mucosal immunization achieves the desired effects of stimulating nasal mucosal IgA and IgG which is protective.

In particular applicants suggest that Hartford lacks a teaching of the stimulation of mucosal immunity and that Hartford does not teach or suggest a composition comprising the *Streptococcus equi* strain in combination with an immunostimulant that has the property of inducing protective immunity in horses. In response, if Hartford did teach such, the examiner suggests the reference would be a 102 reference. However, the examiner maintains as set forth previously and above that Timoney, Hartford and Estrada together render the claimed invention obvious. Applicants argue that Hartford does not teach the challenge and testing of an efficacious vaccine in horses.

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Applicants argue that a person of ordinary skill in the art would not expect to enhance the protective immunity of a live vaccine in an animal if that vaccine had not been demonstrated to be protective for that animal. In response, Timoney and Hartford both evidence that mouse models are routinely used to establish protective vaccines in horses, see in particular Hartford, p. 3, lines 20-21, 49-51, and p. 6 lines 13-16 which teach the induction of protection against lethal intranasal challenge. Their use is advantageous because of ease of use, financial feasibility, and the predictive nature of taking such results from mice to the equine animal model. Furthermore, Timoney expressly teaches vaccination in horses, see in particular Column 5. Estrada need not explicitly state that Q. Saponin promotes mucosal immunity per se. Estrada with Timoney and Hartford render the claims obvious as previously set forth and reiterated herein. The examiner has not used hindsight reconstruction and Estrada and Hartford do suggest with Timoney that combination of the vaccine with Q. Saponin would be obvious to the skilled artisan given a knowledge of Q. Saponins affect in stimulating mucosal IgG and IgA, a requirement for such stimulation for protection and an expectation of success given similar success using such formulations as taught in Hartford and Estrada. The resultant vaccine would be expected to provide the intrinsic properties of obtaining an efficacious vaccine composition which induces protective immunity in horses. Thus, the references cumulatively provide both the suggestion of making the invention and an expectation of success. Therefore the claimed invention is rendered obvious to the skilled artisan at the time of the invention.

#### **Status of Claims**

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9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to



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reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
December 23, 2000

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*